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510(K) Summary of Effectiveness and Safety

The following summary is provided in pursuant to Section 513(I)(3)(A) of the Federal Food, Drug, and Cosmetic Act.

A. Applicant Information

- **Submitter:** Orthotic Solutions, LLC 2802 Merrilee Drive, Suite 100, Fairfax, VA 22031
- **Contact:** Joseph F. Terpenning, CO; Cindy Fox, CPO FAAOP; Luke Stikeleather, CO, President, Telephone: (703) 849-9200, Facsimile: (703) 849-8499
- **Summary Date:** January 26, 2001

B. Device Name and Classification

- **Proprietary Name:** Static Cranioplasty Orthosis
- **Common Name:** Cranial Orthosis
- **Classification Name:** Cranial Orthosis
- **Predicate Device:** DOC™ Band, Cranial Orthosis, K964992, classified under 21 CFR § 882.5970

C. Device Description

The Static Cranioplasty Orthosis is a cranial orthosis used to treat abnormally shaped craniums in infants three to 18 months of age. This condition is clinically known as positional or Deformational Plagiocephaly. The orthosis contains the protruding aspects of the cranium in a static equilibrium while guiding the growth of the flattened areas of the skull into the created spaces. The Static Cranioplasty Orthosis is only available if prescribed by a physician.

The orthosis is custom designed for each patient from a mold of the infant's head. The mold is modified and prepared for fabrication by the treating practitioner using mathematical analyses and plaster modification techniques. The orthosis is then fabricated by the same practitioner. Each orthosis is composed of an outer shell of thermoformable plastic, an inner lining of hypoallergenic foam, a strap for securing the orthosis, and a polymer hinge and guiding system to maintain proper alignment of the orthosis. Optimum fit and alignment is insured and monitored by the same clinical practitioner.

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D. Intended Use

The Static Cranioplasty Orthosis is intended for medical purposes to passively hold prominent cranial regions of an infant's skull in order to improve cranial symmetry and/or shape in infants from three to 18 months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic patterned head shapes.

E. Comparison to Predicate Device

The Static Cranioplasty Orthosis and the predicate device are very similar with respect to production, instructions for use, materials, safety end effectiveness, and special controls. The most significant difference between the two products is the type of thermoformable polymer used for the Static Cranioplasty Orthosis. This device utilizes Durr Plex, an optically clear polymer that allows the practitioner and the parent immediate feedback as to the condition of the child's underlying skin, thus providing an early arrest of any potential skin insults. The material is handled in an identical manner to the polymer used in the predicate device, incorporating all of the safety and standards of practice. The proposed indications of use are analogous to those presented by the predicate device, and biocompatibility, function, and effectiveness further parallel those of the predicate device.

F. Performance Data

The effectiveness of the Static Cranioplasty Orthosis has been established through clinical trials identical to those conducted using the predicate device. The effects of treatment with cranial orthoses on infants have concluded that the devices are significantly effective in correcting abnormal head shape, without evidence of relapse following treatment. Treatment with cranial orthoses is reported to improve the results of surgical correction of severe cases, often eliminating the need for further surgical intervention. Results from a pilot study conducted using the Static Cranioplasty Orthosis have determined that the device is significantly effective in realigning the asymmetrical craniums of infants, and no abnormal reactions or relapses were recorded during the study or during long term follow-ups. Statistical analyses of data collected during pre-treatment and post-treatment assessments support these findings. The Static Cranioplasty Orthosis performed almost uniformly to the predicate device during respective trials, with minor differences attributed to normal inconsistencies in data collection and deviation within normal scientifically acceptable parameters.

The safety of the cranial orthoses is established under standard biocompatibility assessments for each material used. These assessments reveal that the device and the materials used are not expected to adversely affect the infants under the intended conditions of wear. The materials are not reported to cause skin irritation or any toxic effects. Further, the product is designed to avoid improper migration or harmful levels of

pressure. The interior of the device is smooth and poses no significant threat to the child during application within the normal scope of its intended use.

G. Summary

The safety and effectiveness data submitted to the FDA establishes that the Static Cranioplasty Orthosis is safe and effective for its intended use and is substantially equivalent to applicable predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 5 2001

Mr. Joseph F. Terpenning, C.O.
Orthotic Solutions, Inc.
2802 Merrilee Drive, Suite 100
Fairfax, Virginia 22031

Re: K010273
Trade Name: Cranial Molding Orthosis
Regulation Number: 882.5970
Regulatory Class: II
Product Code: MVA
Dated: January 26, 2001
Received: January 29, 2001

Dear Mr. Terpenning:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010273

Device Name: STATIC CRANIOPLASTY ORTHOSIS

Indications For Use:

The Static Cranioplasty Orthosis is intended for medical purposes to passively hold prominent cranial regions of an infant's cranium in order to improve cranial symmetry and/or shape in infants from three to 18 months of age, with nonsynostotic positional plagiocephaly, including infants with plagiocephalic, brachycephalic, and scaphocephalic patterned head shapes.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010273

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)